

April 15, 2022

VDH COVID-19 Therapeutics Bi-Weekly Update

Total Allocations to Therapeutic Provider Sites (04/04/2022 to 04/17/2022):

Therapeutic (mAB & OAV*)	Central	Eastern	Northern	Northwest	Southwest	Total
Bebtelovimab	35	145	185	180	70	615
EVUSHELD	168	144	264	312	48	936
Lagevrio (Molnupiravir)	0	48	0	0	0	48
Paxlovid	40	40	140	100	0	320
Total	243	377	589	592	118	1,919

Oral Antiviral*	Albertsons	CVS	Rite Aid	Topco	Total
Lagevrio (Molnupiravir)	0	168	72	0	240
Paxlovid	460	700	60	40	1,260
Total	460	868	132	40	1,500

*Oral Antiviral numbers presented do not include those allocated to Community Pharmacy Enhanced Services Network. These Oral Antiviral courses were bulk ordered and distribution to individual site locations is managed by respective Federal Retail Pharmacy Therapeutic Program (FRPTP) partners, VDH does not have visibility of course distribution to each region.

*Please reference the Outpatient Therapeutic Portfolio - Jurisdiction Allocations for more detail.

New Paxlovid Dose Pack Authorized by FDA

On April 14, 2022, the U.S. Food and Drug Administration (FDA) revised the Emergency Use Authorization (EUA) for the COVID-19 oral antiviral therapeutic Paxlovid to authorize an additional dose pack presentation with appropriate dosing for patients with moderate renal impairment within the scope of the EUA. As a result, Paxlovid will soon be available in two package presentations:

1. The standard packaging that is currently in distribution: 300 mg nirmatrelvir; 100 mg ritonavir.
2. The new packaging option that will be in distribution later this month: 150 mg nirmatrelvir; 100 mg ritonavir - Each carton contains 20 tablets divided in 5 daily-dose blister cards. Each blister card contains 2 nirmatrelvir tablets (150 mg each) and 2 ritonavir tablets (100 mg each). Nirmatrelvir tablets and ritonavir tablets are supplied in separate blister cavities within the same child-resistant blister card.

More information regarding the additional dose pack presentation for Paxlovid and timing for when this option will be included in allocations for ordering and distribution will be forthcoming.

Therapeutics Requests in VaxMaX

- NEW: A [VaxMaX ordering Job Aid](#) has been created and is located on our [COVID-19 Therapeutics webpage](#).
- Please submit all Therapeutics requests by 12pm ET on Tuesdays in VaxMaX.
- All Therapeutics can be requested in [VaxMaX](#). Once logged into your VaxMaX account, go to the Provider Portal tab, and click "Request Therapeutics".
- When requesting Therapeutics, request based on the number of courses you would like your facility to receive.
- Federal Retail Pharmacy Partners (FRPP) may be able to request Therapeutics in VaxMaX now. Speak with your retail pharmacy chain to learn more.

Update on HRSA Policy

On 03/22/2022, Health Resources & Services Administration (HRSA) announced that the [HRSA COVID-19 Uninsured Program \(UIP\)](#) and [HRSA COVID-19 Coverage Assistance Fund \(CAF\)](#) will stop accepting claims for testing, treatment of COVID-19 due to a lack of sufficient funds. HRSA has notified all enrolled providers of this program update.

For more information:

- [Uninsured Program Portal](#)
- [Uninsured Program webpage \(hrsa.gov\)](#)
- [FAQs about the submission deadline](#)

Update on Sotrovimab Deauthorization

On Tuesday April 5th, the **FDA deauthorized sotrovimab in all regions**, due to the prevalence of the Omicron BA.2 variant greater than 50%. Sotrovimab is no longer available to order and should not be administered to treat Omicron BA.2.

Sotrovimab may be effective against future variants, therefore HHS is recommending that sites with sotrovimab keep current inventory at this time.

Virginia medical providers may wish to use alternate COVID-19 therapeutics such as paxlovid, the preferred drug for COVID-19 treatment, per the [NIH Treatment Guidelines](#), remdesivir (Veklury), bebtelovimab, or Lagevrio (molnupiravir).

Extended Expiration Dates on Sotrovimab / Paxlovid

Drug Name	Lot #	Extended Expiration Date
Sotrovimab	658W	08-2022
	XV6W, Y74D, JP9Y, 287F	10-2022
	287X, 432U, 433C, BX3T	11-2022
	9W8S, A39T	03-2023
	BD8F, BC9P, C86N, CC3D, CK9V, D74S	04-2023
	J23C, JJ7J, J67D	06-2023
	MJ8W, ME3Y, MJ8X, ME3Y, NM9X, NM6J, NX3P, PK8J	07-2023
	RM3K, S63E, R97L, S94Y, TE4L	08-2023
Paxlovid	FL4516, FL4517, FR7229	The initial 3 lots were extended from 7/31/22 to 10/31/22
	FR9088	4 th lot was extended from 8/31/22 to 11/30/22

Test to Treat Program

- The goal of the new Test to Treat program is to increase access to lifesaving treatments that must be given quickly to be effective, particularly for individuals who don't have ready access to a health care provider.
- COVID -19 Treatments delivered as part of Test to Treat Program must be taken within 5 days of initial COVID -19 symptoms.
 - Helps close the gap between positive COVID -19 test and receiving treatment for those eligible.
 - Helps prevent escalation to severe disease, hospitalization, and even death among those at highest risk.
- The Test to Treat Program supports the Biden-Harris Administration [National COVID-19 Preparedness Plan](#).
- The Program builds upon the existing distribution of oral antivirals we are already making available at no cost to thousands of locations across all states and territories and 200 HRSA -funded community health centers nationwide. We have enough oral antivirals [Paxlovid and Lagevrio (molnupiravir)] to provide.
- The Test to Treat locator went live on 03/30/22
 - Please find the locator [here](#)
 - This model leverages pharmacies for end-to-end services, however, it is not limited to just pharmacies.

Therapeutics Return Process for bam/ete and REGEN-COV Products

- All mAb products are property of the USG and must be used in accordance with EUA guidance.
- Sites of care cannot donate products to entities outside the U.S. or for use outside the U.S.
- Any returned product will be destroyed, as product integrity cannot be verified.
- Non-expired product should not be destroyed. Returns only on damaged products or quality concerns.
- Considerations for return process for bam/ete and REGEN-COV products:
 - All sites should first check with respective state and local health department(s) to ensure product cannot be used elsewhere in the state or region
 - Long-term utility of authorized mAb product is expected
 - Upon these considerations, if undamaged product needs to be returned, follow the below instructions:
 - For bam and bam/ete, see The Lilly Return Goods Procedure, detailed guidance can be found at: <https://www.lillytrade.com/>
 - For REGEN-COV, call 844-734-6643
 - Reconstituted (diluted) product SHOULD NOT be returned and should be treated as waste per your facility's SOP

Therapeutic Wastage Reporting Requirements

- As part of a new feature in the Health Partner Order Portal (HPoP), providers are now able to report therapeutic wastage in the portal.
- **Reporting of wastage is required only if therapeutics in your inventory expire and/or will not be used at a future date**
- For information regarding how to report therapeutic wastage in HPoP, please refer to the updated HPoP Job Aid [here](#)
- **If you are having challenges with reporting or have questions, please contact COVID19Therapeutics@vdh.virginia.gov for assistance**
- Unused products that are still in date should not be discarded/destroyed and reported as wastage
- There is currently no way to report wastage for "legacy therapeutics" (meaning those whose EUAs have been revoked). All that providers can do for Bamlanivimab is return wasted products (see: Therapeutics Return Process for bam/ete and REGEN-COV Products)

COVID-19 Therapeutics Webinars and Open Forum Calls

- VDH will facilitate one open forum call in April, as well as one webinar and one open forum call in May. Registration is required:
 - April
 - Open Forum: [04/26/2022](#)
 - May
 - Webinar: [05/12/2022](#)
 - Open Forum: [05/25/2022](#)

If you have any questions, please reach out to covid19therapeutics@vdh.virginia.gov.